

**DEBARMENTS AND SUSPENSIONS BASED ON RESEARCH IMPROPRIETY
IN VA RESEARCH**

1. PURPOSE. This Veterans Health Administration (VHA) Handbook establishes procedures and other requirements for processing debarments and suspensions based on research impropriety in Department of Veterans Affairs (VA) research.

2. SUMMARY OF MAJOR CHANGES. This is a new VHA Handbook that:

a. Creates written procedures for a further, limited implementation of the VA Governmentwide Debarment and Suspension (Nonprocurement) regulation at Title 2 Code of Federal Regulations (CFR) Part 180, as implemented by 2 CFR Part 801. This implementation of 2 CFR Parts 180 and 801 is limited to debarments and suspensions based on research impropriety in VA research.

b. Fulfills the recommendation set forth in the Office of the General Counsel opinion VAOPGCADV 6-2005 (June 2, 2005).

3. RELATED ISSUES. VHA Directive 1058 and VHA Handbook 1058.2.

4. RESPONSIBLE OFFICE. The Office of Research Oversight (10R) is responsible for the contents of this Handbook. Questions may be referred to (202) 565-4835.

5. RESCISSIONS. None.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working day of November 2012.

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DISTRIBUTION: CO: E-mailed 1/18/2008
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mail 1/18/2008

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DEBARMENTS AND SUSPENSIONS BASED ON RESEARCH IMPROPRIETY IN VA RESEARCH

1. PURPOSE

This Veterans Health Administration (VHA) Handbook establishes procedures and other requirements for processing debarments and suspensions based on research impropriety in Department of Veterans Affairs (VA) research.

2. BACKGROUND

a. In 1986, Executive Order 12549, “Debarment and Suspension,” gave governmentwide effect to each Federal agency’s nonprocurement debarments and suspensions. Each Federal agency adopted a set of policies and procedures known as the nonprocurement debarment and suspension common rule to implement that Executive Order. VA implementation of the nonprocurement debarment and suspension common rule was originally codified at Title 38 Code of Federal Regulations (CFR) Part 44. In 2006, the nonprocurement debarment and suspension common rule was re-codified at 2 CFR. Title 2 CFR Subtitle A (Part 180) contains the Office of Management and Budget (OMB) Guidelines to Agencies in Governmentwide Debarment and Suspension (Nonprocurement) (hereafter, “NCR”), and 2 CFR Subtitle B contains each Federal agency’s implementing regulation. VA’s implementing regulation is found at 2 CFR Part 801 (hereafter, “VA Nonprocurement Debarment Regulation”).

b. The NCR, as supplemented by the VA Nonprocurement Debarment Regulation, sets forth general procedures for initiating and processing nonprocurement debarment and suspension actions against persons to exclude them from Federal programs in order to ensure the integrity of these programs. That set of regulations, however, does not encompass all of the procedural details necessary for executing specific debarment and suspension actions within VA. This Handbook provides the necessary details for processing, when appropriate, nonprocurement debarment and suspension actions against persons based on their involvement in research impropriety in VA research.

c. The Office of Research Oversight (ORO) serves as the primary VHA office that advises the Under Secretary for Health on all compliance matters related to human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, and other research improprieties (see Title 38 United States Code (U.S.C.) §7307, and VHA Directive 1058). **NOTE:** *Other research compliance matters not specified (e.g., financial misconduct) fall outside of ORO’s jurisdiction.*

3. PRINCIPLES

a. Under Federal regulations, a person may be excluded from participating in a broad spectrum of federal transactions based on causes such as conviction of or civil judgment for certain offenses, violation of the terms of a public agreement or transaction so serious as to affect the integrity of an agency program, and any cause of so serious or compelling a nature that it affects the person’s present responsibility (see Title 2 CFR §180.800). Governmentwide

exclusions based on such causes are called debarments and take effect following a series of prescribed procedures. A suspension, on the other hand, is an immediate exclusion for a temporary period, pending completion of an agency investigation and any judicial or administrative proceedings that may ensue. Debarments and suspensions are implemented to protect the public interest rather than as disciplinary measures.

b. Federal regulations provide that suspension and debarment actions are to be handled as informally as practicable, consistent with principles of fundamental fairness. Nothing in this Handbook is to be construed to limit or restrict the informality permitted to the Under Secretary for Health under the regulations.

4. SCOPE

a. This Handbook prescribes procedures for debarring and suspending persons who engage in research impropriety in VA research, and the inclusion of those persons on the consolidated list of debarred, suspended, or ineligible persons (see par. 8). Research impropriety refers to noncompliance with the laws, regulations, and policies regarding human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, and research misconduct. It does not encompass improper procedures or conduct in areas outside of the mandate of ORO (for example, waste, fraud, abuse, or fiscal mismanagement).

b. These procedures apply to the debarment or suspension of all persons engaged in, or requesting support for, VA research (see subpar. 5m), including VA employees, “without compensation” (WOC) employees, contractors, and Intergovernmental Personnel Agreement (IPA) personnel. This includes, but is not limited to: scientists, trainees, technicians, other staff members, students, fellows, guest researchers, and collaborators.

c. When more than one Federal agency has an interest in a suspension or debarment covered by this Handbook, the agencies may consider designating one agency as the lead agency for making the decision. The procedures in this Handbook apply when either:

(1) VA is the only Federal agency with an interest in a suspension or debarment, or

(2) Additional Federal agencies have an interest in a suspension or debarment, and VA is designated as the lead agency.

NOTE: Nothing in this Handbook precludes VA from settling a debarment or suspension action at any time, if it is in the best interest of the Federal Government. Voluntary exclusions, in which Respondents agree to be excluded from specified transactions, have governmentwide effect (see 2 CFR 180.640).

5. DEFINITIONS

a. **Covered Transactions.** Covered transactions are all Federal transactions in which persons suspended or debarred may not be a participant or principal except under limited circumstances. These covered transactions are further defined at 2 CFR Part 180, Subpart B and

the VA Nonprocurement Debarment Regulation. Covered transactions include conducting VA research and applying for or receiving approval to conduct VA research.

b. **Debarment.** For purposes of this Handbook, debarment is an action taken by the Under Secretary for Health to exclude a person from participating in the covered transactions listed in the NCR, as supplemented by the VA Nonprocurement Debarment Regulation, and transactions covered under the Federal Acquisition Regulation (48 CFR Ch. 1). A person so excluded is debarred.

c. **Fact-finding.** Fact-finding is a gathering of facts, which is accomplished through:

- (1) Informal meetings with the person subject to these debarment or suspension proceedings;
- (2) Submissions of information, either orally or in writing, by the person; and
- (3) Any other method deemed appropriate by the Under Secretary for Health, or designee.

d. **Notice.** Notice means a written communication served in person, sent by certified mail, or its equivalent, or sent electronically by e-mail or facsimile.

e. **Person.** Person means any individual, corporation, partnership, association, unit of government, or legal entity, however organized.

f. **Research Impropriety.** Research impropriety refers to noncompliance with the laws, regulations, and policies regarding human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, and research misconduct. It does not encompass improper procedures or conduct in areas outside of the mandate of ORO (for example, waste, fraud, abuse, or fiscal mismanagement).

g. **Research Misconduct.** Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. *NOTE: The terms "fabrication," "falsification," and "plagiarism" are further defined in VHA Handbook 1058.2.*

h. **Respondent.** A Respondent is a person against whom VA has initiated a debarment or suspension action.

i. **Standard of Proof.** In any debarment action, VA must establish the cause for debarment by a preponderance of the evidence. If the proposed debarment is based upon a conviction or civil judgment, the standard of proof is met.

j. **Suspension.** Suspension is an action taken by the Under Secretary for Health that immediately prohibits a person from participating in the covered transactions listed in the NCR, as supplemented by the VA Nonprocurement Debarment Regulation, and the Federal Acquisition Regulation (48 CFR chapter 1) for a temporary period, pending completion of an investigation and any judicial or administrative proceedings that may ensue. A person so excluded is

suspended. A suspension may be followed by debarment proceedings, but the imposition of a suspension is not a prerequisite for initiating a debarment action.

k. **Under Secretary for Health.** The Under Secretary for Health is the suspending official for VHA (see VA Nonprocurement Debarment Regulation, 2 CFR §801.1010(a)), and is authorized to impose suspensions against persons who are suspected to have engaged in research impropriety in VA research. As the VHA debarment official (see VA Nonprocurement Debarment Regulation, 2 CFR §801.930(a)), the Under Secretary for Health is authorized to impose debarments against persons who are found to have engaged in research impropriety in VA research.

l. **VA Facility.** A VA facility is a component of the VA national health care system, such as a VA Medical Center, VA Health Care System, or VA Medical and Regional Office Center.

m. **VA Research.** VA research is:

(1) A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge; it is the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. Research includes:

(a) Biomedical research, mental illness research, prosthetic and other rehabilitative research, and health-care-services research; and

(b) All basic, applied, and demonstration research in all fields of science, engineering, and mathematics, including, but not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

(2) All research that:

(a) Is funded or supported in whole or in part by VA;

(b) Is conducted by VA employees within the scope of their VA employment (whether full-time, part-time, WOC, or IPA);

(c) Utilizes VA facilities, resources, or equipment; and/or

(d) Has been approved or authorized by a VA facility's Research and Development (R&D) Committee.

n. **Veterans Integrated Service Network (VISN).** A VISN is a designated regional service within the VA medical system. Each VA medical facility belongs to a geographically-determined VISN and reports to the Director of that service. **NOTE:** *For purposes of this Handbook, "VISN Director" means the VISN Director or designee.*

o. **Voluntary Exclusion.** A voluntary exclusion is a person's agreement to be excluded under the terms of a settlement between the person and one or more agencies. A voluntary exclusion must have governmentwide effect.

6. SUSPENSION

a. **Suspension Recommendations.** Any VA employee may recommend a suspension covered by this Handbook. Such recommendations must adhere to the following requirements:

(1) Suspension recommendations must be supported by documentary evidence that the conditions set forth in the NCR at 2 CFR §180.700 exist. For purposes of this Handbook, the cause for suspension must also be based on research impropriety in VA research.

(2) Except as provided in subparagraph 6a(4), suspension recommendations must be made through normal reporting channels to the appropriate VA facility Director. The facility Director then forwards the recommendation, if it meets the requirements of subparagraph 6a(1), directly to the Under Secretary for Health, through ORO, with a copy to the facility's VISN Director. If the Facility Director decides not to forward the recommendation to the Under Secretary for Health, the reasons for that decision must be placed in writing and included in the record.

(3) ORO has the prerogative to make its own suspension recommendations directly to the Under Secretary for Health.

(4) If a suspension is recommended against a Facility Director or a VISN Director, the recommendation may be made directly to ORO. After ORO determines that the suspension recommendation is procedurally sufficient, ORO forwards the recommendation to the Under Secretary for Health.

b. **Decision to Suspend.** A suspension is effective when the Under Secretary for Health signs a decision to suspend.

(1) To impose a suspension, the Under Secretary for Health must determine that the conditions set forth in the NCR at 2 CFR §180.700 exist.

(2) In issuing a suspension, the Under Secretary for Health must consider the factors specified in the NCR at 2 CFR §180.705. The decision whether or not to impose a suspension is within the full discretion of the Under Secretary for Health.

c. **Notice of Suspension.** After the Under Secretary for Health signs a decision to suspend, ORO issues a notice of the suspension to the Respondent on behalf of the Under Secretary for Health.

(1) The notice of suspension is prepared according to the requirements of the NCR at 2 CFR §180.715 and specifies the terms of the suspension. Copies of the Under Secretary's decision, NCR, VA Nonprocurement Debarment Regulation, and this Handbook are to be included with the notification.

(2) The notice of suspension may be sent to the Respondent, the Respondent's identified counsel, and/or the Respondent's agent for service of process, or any of the Respondent's partners, officers, directors, owners, or joint-venturers.

(3) There must be an effective receipt of the notice of suspension, which is defined as follows:

(a) When delivered, if mailed to the last known street address, or 5 days after the notice is sent if it is undeliverable;

(b) When sent, if sent by facsimile, or 5 days after the notice is sent if the facsimile is undeliverable; or

(c) When delivered, if sent by e-mail, or 5 days after the notice is sent if the e-mail is undeliverable.

d. **Failure to Respond.** If no reply to the notice of suspension is received from the Respondent, or other individual specified in subparagraph 6c(2), within 30 days after effective receipt of the notice, the case is referred to the Under Secretary for Health for a decision to continue, modify, or terminate the suspension on the basis of information available.

e. **Contesting a Suspension.** The Respondent may contest a suspension by providing the Under Secretary for Health with information in opposition to the suspension within 30 days after effective receipt of the notice of suspension.

(1) The Respondent may contest the suspension orally or in writing.

(2) If the Respondent chooses to contest the suspension orally, the Respondent must make arrangements to appear and present the information and argument to the Under Secretary for Health within 30 days after effective receipt of the notice of suspension. Any information that the Respondent considers important must also be submitted in writing for the official record.

(3) In addition to any information and argument in opposition to the suspension, the Respondent must submit the information specified in the NCR at 2 CFR §180.730.

(4) The Respondent may authorize a representative to perform any of the functions contained in this subparagraph 6e.

f. **Additional Fact-Finding.** If the Respondent contests a suspension orally or in writing according to the requirements of subparagraph 6e, additional fact-finding must be conducted as follows:

(1) Only those submissions that raise a genuine dispute over facts material to the suspension are subject to additional fact-finding.

(2) No additional fact-finding is to be conducted if any of the conditions listed in the NCR at 2 CFR §180.735(a) exist.

(3) The Under Secretary for Health must appoint a designee to conduct the fact-finding and present the facts to the Under Secretary for Health for consideration and action.

(4) The fact-finding normally consists of informal meeting(s) between the Under Secretary for Health's designee and the Respondent, the Respondent's representative (at the option of the Respondent), an ORO representative, and counsel from the Office of the General Counsel (OGC).

(a) The Respondent may submit documentary evidence, present witnesses, and confront any witness ORO presents.

(b) A transcribed record of the proceedings must be made available at cost to the Respondent upon request, unless the Respondent and ORO, by mutual agreement, waive the requirement for a transcript.

(5) The Respondent may opt to forgo the in-person meeting provided for under subparagraph 6f(4) and, instead, submit documents to the Under Secretary for Health's designee for review. The Respondent's forgoing of an in-person meeting does not limit the designee's ability to conduct in-person meetings with ORO, any witnesses that ORO may present, and OGC.

(6) The Under Secretary for Health, or designee, may authorize other methods of fact-finding deemed appropriate in addition to, or in lieu of, the method specified in this subparagraph 6f.

(7) Upon completion of the fact-finding, written findings of facts must be provided by the Under Secretary for Health's designee to the Under Secretary for Health for consideration and action, with a copy provided concurrently to ORO.

g. **Under Secretary's Decision.** The Under Secretary for Health makes a decision to continue, modify, or terminate the suspension on the basis of all information available including findings of facts submitted by the designee (subpar. 6f(7)), and arguments submitted by the Respondent.

(1) The Under Secretary for Health may reject any findings, in whole or in part, only after specifically determining them to be arbitrary, capricious, or clearly erroneous.

(2) A written decision to continue, modify, or terminate the suspension must be made within 45 days of receiving final submissions, information, and findings of fact. This period may be extended for good cause.

(3) The period of suspension is determined according to the requirements set forth in the NCR at 2 CFR §180.760.

(4) ORO must provide written notice of the decision to the Respondent on behalf of the Under Secretary for Health.

7. DEBARMENT

a. **Debarment Recommendations.** Any VA employee may recommend a debarment covered by this Handbook. Such recommendations must adhere to the following requirements:

(1) Debarment recommendations must be supported by documentary evidence of a cause listed in the NCR at 2 CFR §180.800. For purposes of this Handbook, the cause for debarment must also be based on research impropriety in VA research.

(2) Except as provided in subparagraph 7a(6), debarment recommendations must be made through normal reporting channels to the appropriate VA facility Director. The facility Director then forwards the recommendation, if it meets the requirements of subparagraph 7a(1), to ORO. If the facility Director decides not to forward the recommendation to ORO, the reasons for that decision must be placed in writing and included in the record.

(3) After ORO determines that the debarment recommendation is procedurally sufficient, ORO forwards the recommendation to the relevant VISN Director.

(4) The VISN Director reviews the debarment recommendation and issues a written opinion agreeing or disagreeing with the recommendation, including the specific reasons for the agreement or disagreement. The VISN Director then forwards the debarment recommendation and written opinion to the Under Secretary for Health, through ORO.

(5) ORO has the prerogative to make its own debarment recommendations directly to the Under Secretary for Health.

(6) If a debarment is recommended against a facility Director, the recommendation may be made directly to ORO; after determining that the debarment recommendation is procedurally sufficient, ORO forwards the recommendation to the relevant VISN Director for review under subparagraph 7a(4). If a debarment recommendation is made against a VISN Director, the recommendation may be made directly to ORO; after determining that the debarment recommendation is procedurally sufficient, ORO forwards the recommendation to the Under Secretary for Health.

b. **Proposed Debarment.** After reviewing a debarment recommendation, the VISN Director's written opinion (where applicable), the causes for debarment in the NCR at 2 CFR §180.800, and any other pertinent document, the Under Secretary for Health decides whether to propose debarment of the named Respondent. The decision whether or not to propose debarment is within the full discretion of the Under Secretary.

c. **Notice of Proposed Debarment.** If the Under Secretary for Health decides to propose a debarment, ORO issues a notice of proposed debarment to the Respondent on behalf of the Under Secretary for Health.

(1) The notice of proposed debarment is prepared according to the requirements of the NCR at 2 CFR §180.805 and specifies the length and terms of the proposed debarment. Copies of the

NCR, VA Nonprocurement Debarment Regulation, and this Handbook are to be included with the notification.

(2) The notice of proposed debarment may be sent to the Respondent, the Respondent's identified counsel, and/or the Respondent's agent for service of process, or any of the Respondent's partners, officers, directors, owners, or joint venturers.

(3) There must be an effective receipt of the notice of proposed debarment, which is defined as follows:

(a) When delivered, if mailed to the last known street address, or 5 days after the notice is sent if it is undeliverable;

(b) When sent, if sent by facsimile, or 5 days after the notice is sent if the facsimile is undeliverable; or

(c) When delivered, if sent by e-mail, or 5 days after the notice is sent if the e-mail is undeliverable.

d. **Failure to Respond.** If no reply to the notice of proposed debarment is received from the Respondent, or other individual specified in subparagraph 7c(2), within 30 days after effective receipt of the notice, the case is referred to the Under Secretary for Health for decision on the basis of information available.

e. **Contesting a Proposed Debarment.** The Respondent may contest a proposed debarment by providing the Under Secretary for Health with information in opposition to the proposed debarment within 30 days after effective receipt of the notice of proposed debarment.

(1) The Respondent may contest the proposed debarment orally or in writing.

(2) If the Respondent chooses to contest the proposed debarment orally, the Respondent must make arrangements to appear and present the information and argument to the Under Secretary for Health within 30 days after effective receipt of the notice of proposed debarment. Any information that the Respondent considers important must also be submitted in writing for the official record.

(3) In addition to any information and argument in opposition to the proposed debarment, the Respondent must submit the information specified in the NCR at 2 CFR §180.825.

(4) The Respondent may authorize a representative to perform any of the functions contained in this subparagraph 7e.

f. **Additional Fact-Finding.** If the Respondent contests a proposed debarment orally or in writing according to the requirements of subparagraph 7e, additional fact-finding must be conducted as follows:

(1) Only those submissions that raise a genuine dispute over facts material to the proposed debarment are subject to additional fact-finding.

(2) No additional fact-finding is conducted, if any of the conditions listed in the NCR at 2 CFR §180.830(a) exist.

(3) The Under Secretary for Health must appoint a designee to conduct the fact-finding and present the facts to the Under Secretary for Health for consideration and action.

(4) The fact-finding normally consists of informal meeting(s) between the Under Secretary for Health's designee and the Respondent, the Respondent's representative (at the option of the Respondent), an ORO representative, and counsel from OGC.

(a) The Respondent may submit documentary evidence, present witnesses, and confront any witness ORO presents.

(b) A transcribed record of the proceedings must be made available at cost to the Respondent upon request, unless the Respondent and ORO, by mutual agreement, waive the requirement for a transcript.

(5) The Respondent may opt to forgo the in-person meeting provided for under subparagraph 7f(4) and, instead, submit documents to the Under Secretary for Health's designee for review. The Respondent's forgoing of an in-person meeting does not limit the designee's ability to conduct in-person meetings with ORO, any witnesses that ORO may present, and OGC.

(6) The Under Secretary for Health, or designee, may authorize other methods of fact-finding deemed appropriate in addition to or in lieu of the method specified in this subparagraph 7f.

(7) Upon completion of the fact-finding, written findings of facts are provided by the designee to the Under Secretary for Health for consideration and action, with a copy provided concurrently to ORO.

g. **Under Secretary's Decision.** The Under Secretary for Health makes a decision on the basis of all information available including findings of facts submitted by the designee (see subpar. 7f(7)), and arguments submitted by the Respondent.

(1) The Under Secretary for Health may reject any findings, in whole or in part, only after specifically determining them to be arbitrary, capricious, or clearly erroneous.

(2) A written decision whether to debar must be made within 45 days of receiving final submissions, information, and findings of fact. This period may be extended for good cause.

(3) ORO provides written notice of the decision to the Respondent, on behalf of the Under Secretary for Health, according to the requirements of 2 CFR §180.870(b).

h. **Period of Debarment.** The period of debarment imposed is based upon the circumstances involved.

(1) Generally, debarment does not exceed 3 years; however, if circumstances warrant, the Under Secretary for Health may impose a longer period of debarment.

(2) The Under Secretary for Health must take into consideration the recommended period of debarment, if any (subpar. 7a), and any mitigating and aggravating factors listed in the NCR at 2 CFR §180.860.

(3) At any time during the debarment period, the Under Secretary for Health may decide to remove the debarment, reduce the period of debarment, or amend the scope of the debarment, if indicated, after review of documentary evidence submitted by or on behalf of the Respondent setting forth the appropriate grounds for granting of such relief. Such grounds may be, but are not limited to: newly discovered material evidence, reversal of a conviction, or the elimination of the cause for which debarment was imposed.

i. **Reconsideration.** A debarred Respondent may submit a written request to the Under Secretary for Health to reconsider the debarment decision or to reduce the time period or scope of the debarment.

(1) The Respondent must support the written request for reconsideration with documentation.

(2) The Under Secretary for Health may reduce or terminate the debarment based on factors set forth at 2 CFR §180.880.

j. **Extension of Debarment.** The Under Secretary for Health may extend the debarment period based on factors set forth at 2 CFR §180.885. If an extension of the debarment period is proposed, the procedures outlined in the NCR, as supplemented by the VA Nonprocurement Debarment Regulation, and this Handbook must be followed.

8. EXCLUDED PARTIES LIST SYSTEM (EPLS)

a. The Excluded Parties List System (EPLS) is a widely available source of the most current information about persons who are excluded or disqualified from covered transactions. The EPLS is maintained by the General Services Administration (GSA), and can be accessed at <http://epls.arnet.gov>. When VA takes an action to exclude a person under the nonprocurement or procurement debarment and suspension system, information about the excluded person is entered into the EPLS.

b. For debarments and suspensions taken under this Handbook, ORO is responsible for entering the information listed at 2 CFR §180.520, into the EPLS.

c. In addition to inclusion on the EPLS, ORO may publish the following, for the length of the debarment and/or suspension in any ORO-authorized dissemination (including the ORO website):

(1) The name, affiliation, and debarment or suspension terms of any person debarred or suspended for research improprieties in VA research; and

(2) The cause of the debarment or suspension.

9. REFERENCES

a. Title 2 CFR Subtitle A -- Part 180. OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)

b. Title 2 CFR Subtitle B – Part 801. Department of Veterans Affairs Implementation of OMB Guidance on Nonprocurement Debarment and Suspension.

c. Executive Order 12549, 51 Fed. Reg. 6370 (February 18, 1986) “Debarment and Suspension” (3 CFR 1986 Comp., p. 189).

d. Title 38 U.S.C. §7307. Office of Research Oversight. Public Law 108-170, Sec. 401 (December 6, 2003).

e. VHA Directive 1058, Responsibilities of the Office of Research Oversight.

f. VHA Handbook 1058.2, Research Misconduct.